DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1113B

Food and Drug Administration
7200 Lake Ellenor Drive
Orlando, FL 32809

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-97-17

January 17, 1997

Mr. William E. Chase
President
Body Systems Technology, Inc.
408 Live Oaks Boulevard
Casselberry, Florida 32707

Dear Mr. Chase:

This letter is written in reference to your firm's marketing and distribution of Easy Trim Spray Formula as a combination anorectic stimulant product. This product lists Caffeine and Phenylpropanolamine as active ingredients and lists Niacinamide as both an active and an inactive ingredient. Easy Trim Spray Formula is labeled as an effective appetite control to assist with weight reduction and a stimulant to restore mental alertness. The labeled claims made for this product cause it to be a drug [Section 201(g) of the Federal Food, Drug, and Cosmetic Act].

Niacinamide, as an active ingredient in this product, causes it to be a new drug because Title 21, Code of Federal Regulations, Section 310.545 specifically lists Niacinamide as an active ingredient which is not generally recognized as safe and effective for weight loss products.

Niacinamide, as an inactive ingredient, does not remedy this situation, since this product is then a new drug because of the combination of Phenylpropanolamine and Caffeine as the active ingredients. A Federal Register notice dated November 18, 1983, announced that the Agency would consider products labeled for any purpose and containing the combination of Phenylpropanolamine and Caffeine as the sole active ingredients to be new drugs.

Since this drug is a "new drug", it may not be legally marketed in the United States because no New Drug Application is approved for this product (Section 505).

Easy Trim Spray Formula is adulterated [Section 501(c)] because it is a drug not recognized in an official compendium, and its strength differs from, or its quality or purity falls below that which it purports or is represented to possess.

Analysis of Easy Trim Spray Formula showed that:

- The product contained approximately 92% of the 42 mg. Phenylpropanolamine per 1.5 ml. or approximately 38.5 mg. per 1.5 ml; and,

- The spray delivery system delivered less than 0.24 ml. of product per two sprays instead of the labeled 1.5 ml.

Based on these results, the average delivered dose is 5.9 mg. of Phenylpropanolamine or approximately 14% of the 42 mg. declared on the immediate product label.

This drug is misbranded [Section 502(f)(1)] because its labeling fails to bear adequate directions for use for the condition for which it is offered and is further misbranded [Section 502(a)] in that its labeling is false and misleading in the following aspects:

- It suggests that there is substantial scientific evidence to establish that it is safe and effective for its labeled uses, when in fact, this is not the case;

- It is labeled as delivering 1.5 ml. per dose (2 pump sprays) and it fails to deliver this amount;

- The immediate product label lists the content of Phenylpropanolamine as 42 mg. per 1.5 ml. (2 pump sprays), while other labeling (brochure) states the content as 25 mg. per 3 pump sprays; and,

- The label lists the 42 mg. of Niacinamide as both an active and inactive ingredient.

The Proposed Rule covering Weight Control Drug Products for Over-the-Counter Human Use, published in the Federal Register on February 26, 1982, establishes a total daily dose for Phenylpropanolamine not to exceed 75 mg. If your product delivered the labeled 42 mg. of Phenylpropanolamine per dose, the total daily dose would be 126 mg. This would exceed the established 75 mg. limit and, in itself, would case Easy Trim Spray Formula to be regarded as a new drug.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be implemented.

Your reply should be sent to the Food and Drug Administration, Florida District, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, Attn: Martin E. Katz, Compliance Officer, telephone no. (407) 648-6823, ext. 262.

Sincerely,

Douglas D. Tolen

Douglas D. Tolen
Director, Florida District